

**REMARKS**

Claims 4, 20, and 44-46 are pending. Claim 44 has been amended to correct typographical errors. Claim 4 has been amended to recite that the sample is treated to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of *Bacillus anthracis*. Claim 20 has been amended to recite that the sample is treated to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of *Bacillus thuringiensis*. Support for the amendments to claims 4 and 20 can be found in the specification at page 15, line 4 to page 16, line 27.

**Objection to the claims**

The Examiner has objected to claim 43. Applicants believe that this is a typographical error and that the subject of the objection is claim 44. The period after step (b) of claim 44 has been deleted and a period has been added at the end of the claim. Thus, this objection should be withdrawn.

**Rejection under 35 U.S.C. § 103(a)**

Claims 4, 20, and 44-46 have been rejected as obvious over Hoffmaster et al., Emerging Inf Dis. 2002;8(10):Suppl. 1-12 (“Hoffmaster”) in view of German, Water Sci Tech. 2002;46:191-198 (“German”); Manz, Microbiology 1995;141:29-39 (“Manz”); Eisenman, App Environ Microbiol. 1998;64(4):1264-1269 (“Eisenman”); and Schlimme et al., App Environ Micro. 1999;2754-2757 (“Schlimme”).

The Examiner contends that Hoffmaster discloses identification of *Bacillus anthracis* in environmental samples by RT-PCR, samples tested from dust and vacuum cleaner debris, and elution of swab specimens and environmental samples in an aqueous solution. According to the Examiner, German teaches that there is a need to investigate the composition of street sweeping waste from a predefined collection route. Further, according to the Examiner, Schlimme discloses that *Tetrahymena pyriformis* can be used to detect bacterial toxicants, including two *Bacillus* strains. The Examiner contends that Eisenman discloses that *Tetrahymena* can

concentrate and detect bacteria by hybridization, and that bacteria are densely packed in the food vacuoles of *Tetrahymena*. According to the Examiner, Manz discloses the analysis of environmental isolates to detect *Legionella* in *Tetrahymena pyriformis*.

Applicants respectfully traverse this rejection. No combination of the references discloses or suggests the claimed method of surveillance wherein a sample derived from street debris is treated to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of *Bacillus anthracis* (claim 4) or the bioencapsulation of *Bacillus thuringiensis* (claim 20), introducing *Tetrahymena pyriformis* to the sample, and assaying the sample for *Bacillus anthracis* (claim 4) or *Bacillus thuringiensis* (claim 20).

The Examiner acknowledges that Hoffmaster does not teach samples collected from a city street or introducing *Tetrahymena pyriformis* to the sample. Office Action, p. 4. Hoffmaster also does not disclose or suggest treating such a sample to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of *Bacillus anthracis* or the bioencapsulation of *Bacillus thuringiensis*. German discloses detecting pollutants, particularly heavy metals, in street sweeping waste. German does not disclose or suggest assaying a sample of street sweeping waste for the claimed *Bacillus* species or treating the sample to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of *Bacillus anthracis* or the bioencapsulation of *Bacillus thuringiensis*.

Schlimate discloses a semi-quantitative bioassay using *Tetrahymena pyriformis* to assess bacterial toxicity. See, e.g., Schlimate, p. 2754, left column. Schlimate does not disclose an assay for detecting the presence of *Bacillus* or any particular bacteria. The assay disclosed in Schlimate permits one to determine the toxicity of a known bacteria, i.e., a test bacteria is assayed for its toxicity, not to identify the bacteria. Further, Schlimate does not disclose or suggest treating the test sample to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of the test bacteria, much less to the claimed *Bacillus* species. Indeed, such a step would be superfluous and wasteful because Schlimate does not disclose assaying a mixed bacterial population.

Eisenman discloses that *Tetrahymena* can graze on *Pseudomonas putida* and that hybridization of the ingested *Pseudomonas* in the food vacuoles of *Tetrahymena* can be used to determine the *Tetrahymena* feeding rates. Eisenman does not disclose or suggest: (1) that *Tetrahymena* ingest *Bacillus* bacteria, (2) assaying a sample derived from street debris, and (3) treating such sample to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of the claimed *Bacillus sp.*

Manz discloses that Legionellaceae are able to infect and proliferate within various types of protozoa, including *Tetrahymena pyriformis*. See, Manz at 36, left column. Manz does not disclose or suggest that *Bacillus* can infect *Tetrahymena pyriformis*, nor that *Tetrahymena pyriformis* can ingest *Bacillus*. Further, Manz does not disclose or suggest assaying a sample derived from street debris, and treating such sample to reduce the concentration of bacteria that are preferentially bioencapsulated by *Tetrahymena pyriformis* relative to the bioencapsulation of the claimed *Bacillus sp.*.

In accordance with the above, no combination of the references discloses or suggests the claimed methods wherein a sample of street debris is treated to reduce the concentration of bacteria that *Tetrahymena pyriformis* preferentially bioencapsulates relative to its bioencapsulation of the claimed *Bacillus sp.*, and the sample is assayed for the *Bacillus*. Thus, the rejection of claims 4 and 20 should be withdrawn.

No combination of the references discloses or suggests the method of claims 44-46, wherein the presence of a *Bacillus* spore is detected in a sample of street debris collected from a street sweeper machine by introducing *Tetrahymena pyriformis* to the sample, and assaying the sample for the presence of a *Bacillus* spore. Indeed, no combination of the references discloses or suggests that *Tetrahymena pyriformis* can ingest a spore from any source. Thus, the rejection of claims 44-46 should be withdrawn.

**CONCLUSION**

This amendment is believed to place the application in immediate condition for allowance. It is respectfully requested that all pending claims be allowed and the case passed to issue.

If the Examiner believes that a telephone conversation would help advance the prosecution in this case, the Examiner is respectfully requested to call the undersigned attorney at (212) 527-7634. The Examiner is hereby authorized to charge any additional fees associated with this response to our Deposit Account No. 04-0100.

Dated: November 30, 2009

Respectfully submitted,

Electronic signature: /Irina E. Vainberg/  
Irina E. Vainberg

Registration No.: 48,008  
DARBY & DARBY P.C.  
P.O. Box 770  
Church Street Station  
New York, New York 10008-0770  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant